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# Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet

Donald W. Light, University of Medicine & Dentistry of New Jersey

Joel Lexchin, School of Health Policy and Management, York University, Toronto, Ontario, Canada

This documented fact sheet provides evidence that all drug research by large firms, net of taxpayers' subsidies, is paid for out of domestic sales in each country, with profits to spare. Prices can be lower without jeopardizing basic research for new drugs. More exposure to global price competition would encourage more innovative research and less of the derivative me-too research that now dominates.

In the U.S., the FDA Commissioner, Mark McClellan, and the drug industry are responding to pressures for lower costs by mounting a large campaign to pressure all other affluent countries to raise their prices to U.S. levels. They claim that lower prices do not pay for drug research costs, but we provide evidence that this is untrue. Ultimately, however, such nationalistic arguments are based on regarding basic research and new discoveries, which can happen anywhere, and the cost of trials, which are carried out in the countries deemed most commercially advantageous, as part of national companies and national accounts, when in fact they are part of a global economy for pharmaceutical products.

**FDA Myths**

1. FDA Commissioner, Mark McClellan, holds that other affluent countries like Canada and the UK set their prices for patented drugs so low that they do not pay for research and development (R&D) (McClellan 2003). We can find no evidence to support that claim.

> On the contrary, audited financial reports of major drug firms in the UK, show that all research costs are paid, with substantial profits left over, based solely on domestic sales at British prices (Pharmaceutical Price Regulation Scheme 2002). Likewise, 79 research drug companies in Canada submitted reports showing their R&D expenditures have risen more than 50% since 1995, all paid for by domestic sales at Canadian prices (Patented Medicine Prices Review Board 2002). Sales to the U.S. and elsewhere are in addition to the positive, domestic balance sheets.

2. FDA Commissioner McClellan says that European or Canadian prices are "slowing the process of drug development worldwide" (McClellan 2003). There is no known verifiable evidence to support this claim. In fact, drug research has been increasing steadily in Europe as well as in the U.S., with some countries having a more rapid increase than the U.S. (Patented Medicine Prices Review Board 2002).

3. FDA Commissioner McClellan says that "price controls discourage the R&D needed to develop new products" (McClellan 2003). But there is no known verifiable evidence to support this claim.

> R&D expenditures have been growing rapidly, though it is becoming more and more difficult to discover breakthrough drugs on targets not already hit (Harris 2003). The truth kept from Americans is that first-line treatment for 96% of all medical problems requires only 320 drugs (Laing et al. 2003). In wealthy countries, more drugs might be appropriate to treat people who do not respond to first-line agents.

4. FDA Commissioner McClellan charges that efforts to negotiate lower prices for patented drugs by other countries (and by major employers, unions and governors in the U.S.) are "no different than violating the patent directly" to make cheap copies (McClellan 2003). This charge echoes the drug industry and implies that large buyers seeking better value should be considered a criminal act.

5. FDA Commissioner McClellan paints a picture of other wealthy countries driving down their prices to marginal costs, but the widening gap between prices for patented drugs in the U.S. and other countries is due to drug companies raising U.S. prices, not other countries lowering theirs (Sager and Socolar 2003; Families USA 2003).

6. The "free-rider" problem that McClellan emphasizes can be solved by U.S. prices coming down to European levels, where they will cover all R&D costs, plus profits that are higher than those in most industries.

7. Drug company profits, after all R&D costs, have long been more than double the profits of Fortune 500 corporations. In recent years they have jumped to triple and even quadruple the profits of other major companies (National Institute for Health Care Management 2000). The global firms spend two and a half to three times more for marketing and administration than for research (Families USA 2001).

8. Americans pay for more R&D than any other country because the United States accounts for more sales than any other country. But while the U.S. accounts for 51% of world sales, it took 58% of global R&D expenditures invested in the US to discover only 43% of the more important new drugs (NCEs) (European Federation of Pharmaceutical Industries and Associations 2003). This means that other countries are helping to pay for the large, inefficient U.S. R&D enterprise, the opposite of what the editors of *Business Week* claimed (Business Week editors 2003). William Safire's claim of a "foreign rip-off" as Americans pay for the world's R&D is contradicted by the

facts above (Safire 2003).

**Research is misdirected by the industry, against patients' interests**

9. Most drug innovation provides little or no therapeutic advantage over existing

> Independent review panels plus a major industry review conclude that only 10 - 15 % of "new" drugs provide a significant therapeutic breakthrough over existing drugs and involve a new chemical or molecule (Barral 1996; Prescrire International 2003; National Institute for Health Care Management Research and Education Foundation 2002). Other industry-sponsored figures are much higher but not reliable.

10. The FDA approves drugs that are better than nothing (placebo) but does not test them against the best existing drugs for the same problem. Most research is for "new" drugs to treat problems already treated by other drugs.

11. About 18% of the drug industry's research budget goes to basic research for breakthrough drugs. About 82% goes to derivative innovations on existing drugs and to testing.

> The long-standing survey of basic research by the National Science Foundation estimates that basic research has increased to 18% of the total research and development (R&D) budget for the pharmaceutical industry. It used to be less (National Science Foundation 2003). Industry-sponsored figures based on secret unverifiable data are much higher but not reliable (DiMasi, Hansen, and Grabowski 2003). The 85-90% of "new" drugs that have little therapeutic gain reflects equal protection from competition for much less investment and risk.

12. Congress has repeatedly extended patent protection for drugs beyond what other industries enjoy, despite much higher profits year in and year out. Government protection from normal competition is now more than 50% greater for the drug industry than a decade ago (National Institute for Health Care Management 2000). These incentives reward research into derivative large markets, rather than to finding effective treatments for diseases that have none.

13. These facts constitute the Blockbuster Syndrome: the lure of monopoly pricing and windfall profits for years spurs the relentless pursuit for drugs that might sell more than $1 billion a year, regardless of therapeutic need or benefit. Research projects for the disorders of affluent nations proliferate, as do clinical trials. Doctors are paid like bounty hunters to recruit patients for thousands of dollars each. Most patients get the misimpression that the experimental drug will be better than existing ones (Wolpe 2003). The corruption of professional judgment, ethics and even medical science follow (Williams 2003; Wazana 2000; Barnett 2003; Lexchin, Bero, Djulbegovic et al. 2003; Bekelman, Mphil, and Gross 2003; Villanueva, Peiro, Librero et al. 2003; Fletcher 2003).

**Drug research costs much less than claimed**

14. Drug companies claim to spend 17% of domestic sales on R&D, but more objective data reports they spend only 10% (National Science Foundation 2003). Thus, only 1.8% of sales goes to research for breakthrough new drugs (18% x 10%) (Love 2003).

15. Taxpayers pay for most research costs, and many clinical trials as well.

> In 2000, for example, industry spent 18% of its $13 billion for R&D on basic research, or $2.3 billion in gross costs (National Science Foundation 2003). All of that money was subsidized by taxpayers through deductions and tax credits. Taxpayers also paid for all $18 billion in NIH funds, as well as for R&D funds in the Department of Defense and other public budgets. Most of that money went for basic research to discover breakthrough drugs, and public money also supports more than 5000 clinical trials (Bassand, Martin, Ryden et al. 2002). Taxpayer contributions are similar in more recent years, only larger.

16. The average amount of research funds the drug industry needs to recover appears to be much less than the industry's figure of $800 million per new drug approved (NDA).

> The $800 million figure is based on the small unrepresentative subsample of all new drugs. It excludes the majority of "new" drugs that are extensions or new administrations of existing drugs, as well as all drugs developed by NIH, universities, foundations, foreign teams, or others that have been licensed in or bought. Variations on existing drugs probably cost much less because so much of the work has already been done and trials are simpler.
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> About half of the $800 million figure consists of "opportunity costs", the money that would have been made if the R&D funds had been invested in equities, in effect a presumed profit built in and compounded every year and then called a "cost." Drug companies then expect to make a profit on this compounded profit, as well as on their actual costs. Minus the built-in profits, R&D costs would average about $108 million 93% of the time and $400 million 7% of the time.
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> The $800 million estimate also does not include taxpayers' subsidies via deductions and credits and untaxed profits (DiMasi, Hansen, and Grabowski 2003; DiMasi, Hansen, Grabowski et al. 1991). Net R&D costs are then still lower.
>
> Contrary to some press reports from the industry, screening for new compounds is becoming faster and more efficient and the time from initial testing to approval has shortened substantially (Kaitin and Healy 2000). The large size of trials seems more due to signing up specialists to lock in substantial market share. Advertising firms are now running clinical trials (Bassand, Martin, Ryden et al. 2002; Peterson 2002; Moyers 2002).

17. Because clinical trials have become a high-profit subindustry, trial "costs" appear to be much more than is nec-

essary.

> An international team of experts estimates that clinical trials could be done for about $500 per patient rather than $10,000 per patient, a 95% reduction (Bassand, Martin, Ryden et al. 2002). The most detailed empirical study of trial costs also concludes that costs can be much less than reported (The Global Alliance for TB Drug Development 2001).

**U.S. drug prices very high**

18. Americans seem unaware how much more they are paying for drugs than other countries, in the name of the "free market" where prices are controlled by corporations. So-called "price controls" abroad are negotiated wholesale prices. Corporate price controls in the U.S. are un-negotiated monopoly prices, which then large buyers negotiate down.

> According to a detailed analysis, American employers and health plans pay at wholesale 2.5-3.5 times the prices in Australia and other countries with comparable prices for patented drugs (Productivity Commission of Australia 2001). There is no evidence that these prices do not cover research costs. U.S. generic prices shadow patent drug prices and are also 2.5-3.5 times more.

19. High American prices are essentially monopoly rents charged to employers in every other industry. They shift profits from other industries to the drug industry.

20. If American prices were cut in half, research budgets would not have to suffer unless executives decided to cut them in favor of marketing, luxurious managerial allowances or high profits. They probably would not, because R&D gets such favorable tax treatment compared to other expenses. Lower prices would save other Fortune 500 companies billions in drug benefit costs, and drug company profits could come into line with the profits of the companies who pay for their drugs.

**Realign incentives to reward true innovation**

21. Current incentives strongly reward derivative innovation. We get what we reward.

22. Because the U.S. is by far the biggest spender, it has by far the most R&D and new drugs. Four other industrialized countries, however, devote more of their GDP to R&D for new drugs than the U.S. (Patented Medicine Prices Review Board 2002).

23. Officials of drug companies commonly claim that nearly all new drugs are discovered in the U.S. However, the industry's own studies (and others) show that over the past quarter century, the U.S. has accounted for less than or about the same as its proportionate share of international new drugs, not more and certainly not nearly all (Barral 1996; European Federation of Pharmaceutical Industries and Associations 2000). Until 2002, even the U.S. pharmaceutical industry was investing an increasing percent of its R&D budget in highly productive research teams abroad (Pharmaceutical Research and Manufacturers of America 2002).

24. Americans are getting less innovation and paying a lot more. Competing countries profit from these American self-delusions by covering their R&D and keeping their own drug prices reasonable, while leaving drug companies to make bonanza profits from the monopoly American market.

25. Price competition has been the greatest spur to innovation for over 200 years. Price protections reward derivative and me-too innovation as well as excessive costs and a focus on blockbuster marketing. If we want lower prices and more breakthrough innovations, we need to change the incentives to reward those goals (Baker and Chatani 2002).

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